REMARKS/ARGUMENTS:

Claims 1-30 are pending. Claims 3, 9, 20, and 21 are amended. Support for the amendment can be found, e.g., at page 6, lines 3-19 of the specification. New claims 27-30 are added to separate two species from a genus. No new matter is introduced. Claims 14-26 and 29-30 are withdrawn from consideration.

Group Election

The Examiner required a restriction to one of the following ten groups of the claimed invention:

I. Claims 1, 2, and 4-13, drawn to a method of detecting metastatic melanoma cells in a patient comprising amplifying nucleic acid targets, classified in class 435, subclass 6.

(The Examiner further required that, upon election of Group I, Applicants must select a single marker gene from claim 2 (either MAGE-A3, MART-I, MITF, TRP-2, or Tyrosinase), as each marker represents a separate invention and not a species.)

II. Claims 1 and 3 (in part), as specifically drawn to a method of detecting metastatic melanoma cells in a patient comprising amplifying nucleic acid targets from a panel comprising MAGE-A3, GalNAct, MART-1, and PAX3, classified in class 435, subclass 6.

III. Claims 1 and 3 (in part), as specifically drawn to a method of detecting metastatic melanoma cells in a patient comprising amplifying nucleic acid targets from a panel comprising MART-1, GalNAct, MITF, and PAX3, classified in class 435, subclass 6.

IV. Claims 1 and 3 (in part), as specifically drawn to a method of detecting metastatic melanoma cells in a patient comprising amplifying nucleic acid targets from a panel comprising MART-1, TRP-2, GalNAcT, and PAX3, classified in class 435, subclass 6.

V. Claims 1 and 3 (in part), as specifically drawn to a method of detecting metastatic melanoma cells in a patient comprising amplifying nucleic acid targets from a panel comprising Tyrosinase, MART-1, GalNAcT, and PAX3, classified in class 435, subclass 6.

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VI. Claims 14, 15 (in part), and 16-22, drawn to a method of detecting metastatic breast, gastric, pancreas, or colon cancer cells in a patient comprising preparing paraffin-embedded samples from tissues or lymph nodes of the patient wherein the panel comprises C-Met, MAGE-A3, GalNAcT, and CK20, classified in class 435, subclass 6.

VII. Claims 14, 15 (in part), and 16-22, drawn to a method of detecting metastatic breast, gastric, pancreas, or colon cancer cells in a patient comprising preparing paraffin-embedded samples from tissues or lymph nodes of the patient wherein the panel comprises (presumably mammoglobulin,) C-Met, GalNAcT, and ß-HCG, classified in class 435, subclass 6.

VIII. Claims 14, 15 (in part), and 16-22, drawn to a method of detecting metastatic breast, gastric, pancreas, or colon cancer cells in a patient comprising preparing paraffin-embedded samples from tissues or lymph nodes of the patient wherein the panel comprises (presumably mammoglobulin,) ß-HCG, HSP27, and C-Met, classified in class 435, subclass 6.

IX. Claims 14, 15 (in part), and 16-22, drawn to a method of detecting metastatic breast, gastric, pancreas, or colon cancer cells in a patient comprising preparing paraffin-embedded samples from tissues or lymph nodes of the patient wherein the panel comprises HSP27, CK20, Stanniocalcin-1, and MAGE-A3, classified in class 435, subclass 6.

X. Claims 23-26, drawn to a kit for use in detecting melanoma cells in a biological sample, classified in class 435, subclass 810.

(The Examiner further required that, upon election of Group X, Applicants must select one marker gene from claims 24 (either MAGE-A3, MART-1, MITF, TRP-2, or Tyrosinase), as each marker represents a separate invention and not a species.)

This restriction requirement is respectfully traversed.

A. Restriction within Groups I and X

Group I includes claims 1 and 2. Claim 1 is directed a method of detecting metastatic melanoma cells in a patient comprising:

(a) isolating nucleic acid from a biological sample obtained from the patient;

(b) amplifying nucleic acid targets, if present, from a panel of marker genes, wherein the panel comprises GalNAcT, PAX3, or both; and

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(c) detecting the presence or absence of the nucleic acid targets.

Claim 2 depends from claim 1, wherein the panel further comprises marker genes selected from a group consisting of MAGE-A3, MART-1, MITF, TRP-2, and Tyrosinase.

The Examiner required that, upon election of Group I, Applicants must select a single marker gene from claim 2, either MAGE-A3, MART-I, MITF, TRP-2, or Tyrosinase. Applicants respectfully traverse.

Claim 2 is drawn to a method where one or more of MAGE-A3, MART-1, MITF, TRP-2, and Tyrosinase genes can be included in a marker panel. Limiting the claim to a single gene (MAGE-A3, MART-1, MITF, TRP-2, or Tyrosinase) would destroy a major part of the invention, because combinations of these genes would be excluded. In this connection, Applicants point out that inclusion of additional genes in a marker panel usually increases the specificity, sensitivity, and accuracy of the diagnostic method.

Furthermore, all of these genes (MAGE-A3, MART-1, MITF, TRP-2, and Tyrosinase) are closely related. They are all melanoma-associated genes. As such, the status in the art and the field of search for each of the genes largely overlap. There would be no serious burden on the Examiner if no restriction is required among these genes.

Therefore, Applicants respectfully request that the restriction within Group I be withdrawn. The restriction within Group X should also be withdrawn for similar reasons.

B. Restriction of Groups I-V and VI-IX

As mentioned above, Group I includes claims 1 and 2. Claim 3, as amended, depends from claim 2, wherein the panel may comprise one of four specific combinations of the marker genes recited in claims 1 and 2: MAGE-A3, GalNAcT, MART-1, and PAX3; MART-1, GalNAcT, MITF, and PAX3; MART-1, TRP-2, GalNAcT, and PAX3; and Tyrosinase, MART-1, GalNAcT, and PAX3.

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The Examiner required restriction of Group I (excluding claim 3) and further restriction of Groups II-V (each of which includes claim 1 and a part of claim 3 where one of the four specific combinations of the marker genes is selected). Applicants respectfully traverse.

First of all, Groups I-V are in the same class and even the same subclass. Secondly, all of the marker genes recited in claim 3 (GalNAcT, PAX3, MAGE-A3, MART-1, MITF, TRP-2, and Tyrosinase) are encompassed in claims 1 and 2. Since claim 3 only recites specific embodiments of claim 2, it places no additional burden on the Examiner if claim 3 is not excluded from Group I.

Furthermore, all of the marker genes recited in claim 3 (GalNAcT, PAX3, MAGE-A3, MART-1, MITF, TRP-2, and Tyrosinase) are closely related. They are all melanoma-associated genes. As such, the status in the art and the field of search for each of the genes largely overlap. There would be no serious burden on the Examiner if no restriction is required among the four combinations of these genes.

Therefore, Applicants respectfully request that Groups I-V be combined. Applicants also request that Groups VI-IX be combined for similar reasons.

Species Election

The Examiner required election of a species from disease recurrence, patient's prognosis, and patient's survival recited in original claims 9 and 20. Applicants respectfully traverse.

Patient's prognosis is a generic term, encompassing both disease recurrence and patient's survival. Claim 9, as amended, is directed to a method comprising a step of predicting at least patient's prognosis, determined based on the presence or absence of nucleic acid targets in a sample. New claims 27 and 28 are added, wherein the patient's prognosis is disease recurrence and patient's survival, respectively. Claim 20 is amended and new claims 29 and 30 are added likewise.

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The amendments to claims 9 and 20 render moot the Examiner's requirement for species election because patient's prognosis is generic. Disease recurrence and patient's survival are closely related subsets of patient's prognosis. Prediction of disease recurrence and patient's survival involve similar steps. For example, both methods require determination of the presence or absence of nucleic acid targets in a sample and correlation of the presence or absence of the nucleic acid targets to the outcome of disease recurrence or patient's survival. Therefore, the status in the art and the field of search for each of the methods largely overlap. There would be no serious burden on the Examiner if no restriction is required between these two methods. Therefore, Applicants respectfully request that the requirement for species election be withdrawn.

In view of the foregoing, the Examiner is respectfully requested to withdraw the restriction requirement within Groups I and X, to combine Groups I-V and VI-IX, and to withdraw the requirement for species election within claims 9 and 20.

If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-1314.

Respectfully submitted,
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Date: January 20, 2006

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